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IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re the Application of: **Takeo TANAAMI et al.**

Art Unit: 1797

Application Number: **10/716,417**

Examiner: **Nathan Andrew Bowers**

Filed: **November 20, 2003**

Confirmation No.: **6545**

For: **BIOCHIP CARTRIDGE**

Attorney Docket Number: **032106**

Customer Number: **38834**

SUPPLEMENTAL REPLY BRIEF

Commissioner for Patents
P. O. Box 1450
Alexandria, VA 22313-1450

June 5, 2009

Sir:

In response to the Supplemental Examiner's Answer mailed April 13, 2009, the following is the Appellants' Supplemental Reply Brief.

REMARKS

I. Whether the position in the Examiner's Answer or Supplemental is consistent with the position of the Office Actions.

Appellants briefly argue that the interpretation of the cited art in the Examiner's Answer dated October 1, 2008 and the Supplemental Examiner's Answer dated April 13, 2009 is inconsistent with the positions of the March 7, 2007 and November 13, 2007 Office Actions. Throughout prosecution, Appellants have argued that the proposed modification of Christian would change the apparatus from the "parallel" apparatus to a hybrid "parallel/series" apparatus.

However, in the Examiner's Answer, it is stated that "the proposition of modifying Christian to create a "series" arrangement has always been advanced – never a "parallel/series" configuration." Examiner's Answer, page 13, lines 6-8 (emphasis added). In the Reply Brief, Appellants argued the proposed creation of a "series" arrangement was inconsistent with the March 7, 2007 and November 13, 2007 Office Actions, and that this position was being fully articulated for the first time in the Examiner's Answer.

In the Supplemental Examiner's Answer, the Examiner states that the arguments in the previous Office Actions "strongly suggest[] a series configuration." However, Appellants respectfully submit that the explicit remarks in those previous Office Actions specifically exclude such a "series configuration" and explicitly include the hybrid "series/parallel" configuration which Appellants have been addressing throughout prosecution. For example, on page 12 of the March 7, 2007 Office Action, the Examiner states that "[o]ne would be motivated to modify the existing structure of Christian in order to provide a new sample inlet port, collection area and preprocessing area **while maintaining the existing wash chambers of Christian.**" Thus, it is clear that in the March 7, 2007 Office Action, the Examiner was arguing in support of a hybrid "series/parallel" configuration where the wash chambers are retained, rather than a "series" configuration where the wash chambers are deleted (as illustrated on page 14 of the Examiner's Answer).

Furthermore, on page 12 of the November 13, 2007 Office Action, it is stated that "one of ordinary skill in the art would recognize how to redesign the apparatus of Christian **to ensure that the sample is not needlessly moved into the wash chambers.**" If the Examiner was truly

arguing that it would have been obvious to modify Christian in order to achieve a “series” configuration instead of a hybrid “series/parallel” configuration, then the Examiner would have noted that the wash chambers would be removed, as illustrated in the drawing provided on page 14 of the Examiner’s Answer. In other words, movement of sample into wash chambers would be irrelevant if the wash chambers were deleted, as would be the case in a “series” configuration. Thus, it is clear that in the November 13, 2007 Office Action, the Examiner was arguing in support of a hybrid “series/parallel” configuration where the wash chambers are retained, rather than a “series” configuration where the wash chambers are deleted (as illustrated on page 14 of the Examiner’s Answer).

Additionally, in the Supplemental Examiner’s Answer, in response to Appellants comments about previous Office Actions (discussed above), it is stated that “these arguments by the Examiner were made strictly *in the alternative*” (emphasis in original). Supplemental Examiner’s Answer, page 22. However, Appellants respectfully note that nowhere in the March 7, 2007 Office Action or the November 13, 2007 Office Action was it stated that multiple interpretations of the cited art were being argued by the Examiner in the alternative. Rather, the only interpretation of the cited art presented was the proposed modification of Christian to be a hybrid “series/parallel” device. Therefore, Appellants respectfully submit that contrary to the statements in the Supplemental Examiner’s Answer, the proposed modification of Christian resulting in a hybrid “series/parallel” was not a misinterpretation of the Office Actions. Rather, Appellants respectfully submit that the explicit language of both the March 7, 2007 and

November 13, 2007 Office Actions (discussed above) unambiguously proposed a hybrid “series/parallel” configuration, and unambiguously excluded a “series” configuration.

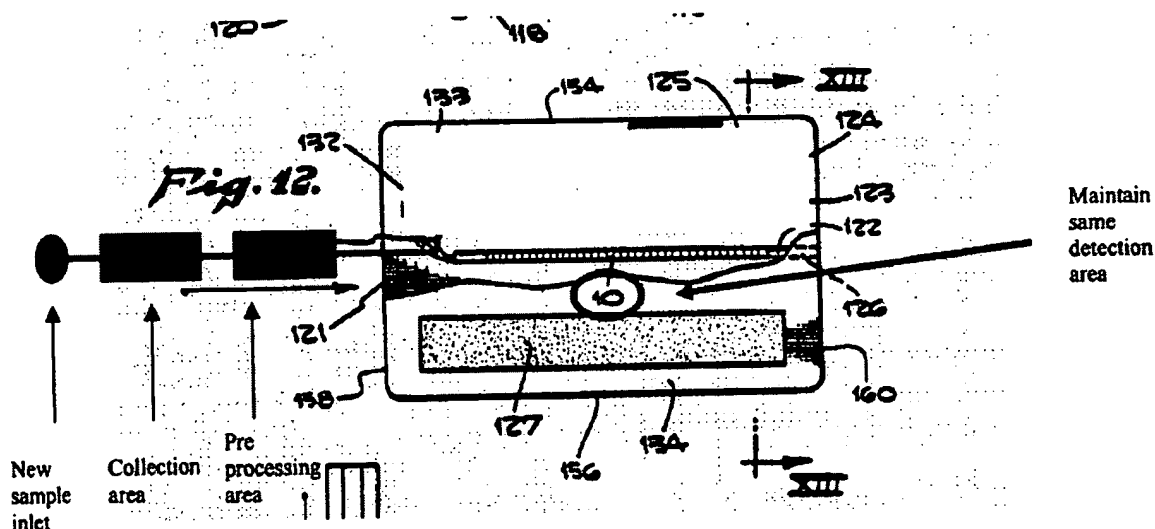
Prior to the Supplemental Examiner’s Answer, the position that “series” and hybrid “series/parallel” configuration were being presented as alternative arguments was only mentioned once in passing in the prosecution history—by the use of the word “or” in the Advisory Action dated May 27, 2008. Furthermore, Appellants note that the Examiner’s Answer argued in support of a “series” configuration, and stated that a “series/parallel” configuration was never argued. Thus, the position in the Examiner’s Answer is not only opposite of the position in the March 7, 2007 and November 13, 2007 Office Actions, but also contradicts the position of the earlier-issued Advisory Action dated May 27, 2008 and the later-issued Supplemental Examiner’s Answer dated April 13, 2009.

Appellants respectfully submit that the Examiner’s position has been constantly changing, frustrating Appellants’ attempts to expedite examination and simplify issues for the Board. In summary, the Examiner has proposed the following modifications of Christian: a hybrid “series/parallel” configuration only (March 7, 2007 Office Action and November 13, 2007 Office Action), “series” or hybrid “series/parallel” configurations in the alternative (Advisory Action dated May 27, 2008), a “series” configuration only (Examiner’s Answer dated October 1, 2008), and finally “series” or hybrid “series/parallel” configurations in the alternative once again (Supplemental Examiner’s Answer dated April 13, 2009). Thus, Appellants respectfully submit that the positions of the Examiner’s Answer and Supplemental Examiner’s Answer are inconsistent with the Office Actions dated March 7, 2007 and November 13, 2007, and are

merely attempts to retroactively revise the arguments of record. Appellants respectfully request that the Board be mindful and aware of these various and changing arguments by the Examiner, and formulate their decision accordingly.

II. The proposed modification of cited art in the Examiner's Answer renders the device of Christian unsuitable for its intended purpose.

As discussed above, the Examiner now revises his position by stating that the proposed modification of Christian should instead be illustrated by the following diagram:



In response to the comments in the Supplemental Examiner's Answer, Appellants respectfully reiterate that the proposed modification, either to a "series" configuration or a hybrid "series/parallel" configuration changes the principle of operation of the device of Christian, as explicitly conceded by the Examiner. Thus, Appellants respectfully submit that it would not have been obvious to combine the cited art as proposed.

However, Appellants herein clarify the remarks in the Reply Brief that the modification of Christian to be a “series” configuration renders the device of Christian unsuitable for its art-recognized purpose. Appellants argued that if Christian, *arguendo*, were to be modified to be a “series” device, all of the reagent, sample and wash solutions would be mixed together before entering the reaction area. Appellants respectfully submit that even if, *arguendo*, Christian as modified could detect multiple antibodies using a single test sample, the device of Christian would still be rendered unsuitable for its intended purpose.

Specifically, Christian relies upon the selective transferring of solutions to and from the detection area. In particular, Christian states that “the microassay card, by its own geometry and design, provides the programming necessary to control the sequencing and timing of the assay protocol.” Column 4, lines 11-13 (emphasis added). For example, Christian states that after “the desired incubation time,” the roller “squeezes the test sample out of the channel 122.” Column 12, lines 40-44. Then, wash solution is transferred to the channel 122. “After a suitable time period,” the wash solution is removed. Column 12, lines 48-50. Then, the desired chromogenic second antibody or other detecting solution is transferred into the channel 122. “After sufficient time to allow the chromogenic second antibody to react,” the chromogenic solution is removed. Column 12, lines 55-56. In other words, the selective transferring of solutions in Christian allows the user to very particularly control the duration of each step of the assay while keeping all solutions self-contained in the microassay card.

Christian further states its configuration allows the user to precisely control the durations of and sequence of various reactions and washing steps which take place in a complex analysis.

Christian explains as follows:

For more complicated analysis procedures in which one or more reagents are necessary to treat the microassay rod in a number of sequential steps, the microassay card in accordance with the present invention includes various raised channel portions in the top plate which are closed off by the pressure bar or rod as it moves across the card top. The raised channel portions provide a particularly convenient and simple means for programming the addition of reagents, buffer solutions and other liquids at selected intervals and in a selected sequence. Column 4, lines 37-47 (emphasis added).

Similarly, the configuration of Christian allows for application to a system where second and third antibodies are used (additional channels would be added). The second antibody would be transferred, allowed to react for the appropriate time, and then removed. After a washing, the third antibody would be transferred, allowed to react for the appropriate time, and then removed. In other words, the selective transferring of solutions in Christian allows the user to very particularly control the duration of each step of a more complicated assay while keeping all solutions self-contained in the microassay card.

If the microarray chip were modified as proposed by the Examiner—removing all chambers except the detection chamber—none of this would be possible. Rather, in the proposed modification, all of the reagents, test samples and wash solutions would be mixed together prior to measuring in the reaction area. It would not be possible to control the amount of time which the test sample is allowed to incubate with the probe in the detection area. It would also not be possible to control the amount of time which the wash solution is allowed to mix with the bound

test sample and probe in the detection area. It would also not be possible to control the amount of time which the second antibody or detection solution is allowed to react with the washed and bound test sample and probe in the detection area. Thus, Appellants respectfully submit that the proposed modification would render the device of Christian unsuitable for its intended purpose. If a proposed modification would render the prior art invention being modified unsatisfactory for its intended purpose, then there is no suggestion or motivation to make the proposed modification. *In re Gordon*, 733 F.2d 900, 221 USPQ 1125 (Fed. Cir. 1984). Therefore, Appellants respectfully submit that it would not have been obvious to combine the cited art as proposed by the Examiner.

Additionally, Appellants respectfully reiterate that the Examiner misapplies *Dilnot* and *Ratti*, and that Christian teaches away from the proposed modification from a “parallel” configuration to a “series” configuration, since Christian stresses the selectivity of the transfer—something that is not possible with a “series” configuration.

In summary, for at least the reasons in the Reply Brief filed November 20, 2008 and the reasons herein, Appellants respectfully submit that the proposed modification of Christian illustrated in the Examiner’s Answer dated October 1, 2008—a “series” configuration—illustrates the fact (i) that the proposed modification changes the principle of operation of the device from a “parallel” device to a “series” device, (ii) that Christian teaches away from the proposed modification, and (iii) that the proposed modification would render the microarray chip of Christian unsatisfactory for its intended use. Therefore, for at least the reasons discussed above, and in the Appeal Brief, Appellants respectfully submit that the pending rejection should

be withdrawn. Additionally, for at least the reasons discussed in the Appeal Brief filed August 6, 2008, Appellants respectfully submit that it would not have been obvious to modify Christian as illustrated in the March 7, 2007 Office Action to arrive at a hybrid “series/parallel” configuration.

III. Lack of a case of *prima facie* obviousness.

In the Supplemental Examiner’s Answer, the Examiner clarifies that the sentence on page 15 of the Examiner’s Answer should have read “[i]t is important to remember that the rejection does not rely on the primary reference alone – in fact, *four* references, each supply ample motivation, have been cited as evidence that a series configuration is obvious,” instead of “[i]t is important to remember that the rejection does not rely on a *prima facie* case of obviousness – in fact, *four* reference, [*sic*] each supplying ample motivation, have been cited as evidence that a series configuration is obvious.”

Appellants thank the Examiner for clarifying his position by making this correction. However, Appellants respectfully reiterate that it is not germane to the rejection that the concept of a “series” configuration was known in the art—something that Appellants do not dispute. As noted by the Supreme Court, “a patent composed of several elements is not proved obvious merely by the demonstrating that each of its elements was, independently, known in the prior art.” *KSR Int’l Co. v. Teleflex Inc.*, 127 S. Ct. 1727, 1741 (2007). Rather, there must be a reason for combining teachings of cited art. This is because “inventions in most, if not all, instances rely upon building blocks long since uncovered, and claimed discoveries almost of necessity will be combinations of what, in some sense, is already known.” *Id.* In other words, even if,

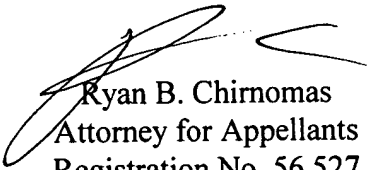
arguendo, four different references provide a disclosure of a “series” configuration, for at least the reasons discussed in the Responses filed August 30, 2007 and May 8, 2008, in the Appeal Brief dated August 6, 2008, in the Reply Brief dated November 20, 2008, and herein, it would not have been obvious to modify the Christian in order to arrive at the apparatus as claimed—whether such a modification resulted in a “series” configuration or a hybrid “series/parallel” configuration.

Thus, for at least the above reasons, Appellant requests that the Honorable Board reverse the Examiner’s rejection.

If this paper is not timely filed, Appellant respectfully petitions for an appropriate extension of time. The fees for such an extension or any other fees that may be due with respect to this paper may be charged to Deposit Account No. 50-2866.

Respectfully submitted,

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